

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in January 2011.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-312

Trade Name: Hexasol™ Injection
Ingredients: Oxytetracycline and flunixin meglumine
Sponsor: Norbrook Laboratories, Ltd.
Approval Date: November 29, 2010
Status: Rx
Route: Intramuscular or subcutaneous injection
Species: Beef and non-lactating dairy cattle
Drug Form: Injectable solution
Concentration: 300 mg oxytetracycline and 20 mg flunixin base as flunixin meglumine per mL
Indications: For the treatment of bacterial pneumonia associated with *Pasteurella spp.* and for the control of associated pyrexia in beef and non-lactating dairy cattle.
Exclusivity: 3 years
Patent: Patent Number 6,479,473 Expiration date: May 6, 2017

21 CFR 522.1664 76 FR 3488

Sponsor Change

NADA Numbers: 141-067

Previous: Biopure Corp.
New Sponsor: OPK Biotech, LLC
Drug Labeler Code: 063075

21 CFR 510.600 76 FR 2807

NADA Numbers: 141-014

Previous: Ausa International, Inc.
New Sponsor: Therio, Inc.
Drug Labeler Code: 052923

21 CFR 510.600 76 FR 2807